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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/831,901 | 08/07/2001 | Kanji Takada | P21010 | 2415 |
| 7055 | 7590 | 10/20/2005 | EXAMINER | |
| GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191 | | | GHALI, ISIS A D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1615 | |

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,901

Applicant(s)

TAKADA, KANJI

Examiner

Isis Ghali

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08/11/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-18 and 20-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-18, 20-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of the advisory action mailed 08/02/2005 is withdrawn.

Claims 1-8, 10-18 and 20-25 are pending and included in the prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 6-8 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,700,478 ('478).

US '478 disclosed a laminated device for oral ingestion for delivering active agents into mucosa-lined body cavity such as gastrointestinal tract or rectum (abstract; col.3, lines 33-34, 49-50; col.33, lines 44-45). The device comprises adhesive layer having thickness of 5-10 mils and made of hydroxypropyl cellulose or methacrylate (both are enteric polymers), a middle polymer layer that contains the active agent loaded in there, and protective layer (col.3, lines 65-66; col.4, lines 50-67; col.7, lines

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25-28; col.8, lines 66-67; col.10, lines 25-43; col.16, lines 52-65; Figure 2). The protective layer is made of polymer and wax (col.4, lines 35-45; col.10, lines 33-43).

Plasticizers are included in the active agent-containing layer, i.e. permeation enhancers (col.7, lines 22-35). Figure 4 shows that the adhesive layer is attached to the protecting layer as required by claim 22.

4. Claims 1, 2, 6-8, 10, 12-14, 16-18, 20, 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,686,105 ('105).

US '105 disclosed dosage form for peroral administration of active agents to small intestine or colon (abstract; col.5, lines 47-52). The dosage form comprises a substrate coated with the active agent containing layer and enteric coated with at least inner and outer coating layer (abstract; col.7, lines 16-20). The substrate disclosed by the reference reads on the instantly claimed protective layer, and the enteric coating layers reads on the adhesion site controlling layer and the capsule. The active agents are included in a polymer layer (col.8, lines 21-23). The substrate is made of wax and polymer (col.8, lines 48-53; col.14, lines 50-60). Active agents to be delivered included proteins and peptides (col.6, lines 46-48). According to the disclosure of the reference, the drug containing layer is sealed between the adhesive layer and the protecting layer as required by claim 23 and also the adhesive layer and the protective layer are attached by the drug containing layer as required by claim 22.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 4, 5, 10, 11, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '478.

The teachings of US '478 are discussed under 102 rejection above.

However the reference does not teach the hemispherical shape of the protective layer, the specific drugs or the sealing of the drug-containing layer between the adhesive and protective layer.

The shape of the protective layer and specific active agents does not impart patentability to the claims, absent evidence to the contrary. The sealing of the active agent-containing layer between the adhesive and the protective layers is well known in the art and widely used in the form of reservoir containing the active agent.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the protective layer in any desired shape and select the active agent as needed with reasonable expectation of having hemispherical capsules to deliver the desired active agent to the lower part of the GIT with success.

8. Claims 12-18, 20, 21, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '478 in view of US 6,231,888 (888).

The teachings of US '478 are discussed under 102 rejection above.

However, US '478 does not teach encapsulation of the laminate.

US '888 teaches an oral device that can be in the form of multilayered composite that can be encapsulated for slow release and preferential metabolism of the delivered agent in the patient's colon (abstract; col.15, lines 65-67; col.30, lines 1-2).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the laminate device disclosed by US '478 to deliver active agents to the GIT, and encapsulate the device in as disclosed by US '888, motivated by the teaching of US '888 that the encapsulated device slows the release and preferential metabolism of the delivered agent in the patient's colon, with

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reasonable expectation of having encapsulated laminated device that deliver desired active agent to patients colon with success.

9. Claims 3, 4, 5, 11, 15, 21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '105.

The teachings of US '105 are discussed under 102 rejection above. US '105 recognized the desire to have oral device free of edges or shape curves for more smooth delivery to the lower GIT (col.7, lines 57-60).

However the reference does not teach the thickness of each layer, hemispherical shape of the protective layer, the specific drugs as claimed in claim 11.

The thickness of the layers does not impart patentability to the claims since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable/ranges involves only routine skill in the art. *In re Aller* 105 USPQ 233.

The shape of the protective layer and specific active agents does not impart patentability to the claims, absent evidence to the contrary.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the protective layer in any shape that has no edges or shape curves as disclosed by US '105, and select the active agent as needed with reasonable expectation of having hemispherical capsules to deliver the desired active agent to the lower part of the GIT with success.

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10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,194,000 teaches oral dosage form coated with enteric coating polymers including hydroxypropyl cellulose (col.4, lines 39-45).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595.


The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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